ABSTRACT

Introduction: Diabetes Mellitus has become one of the common metabolic disorders characterized by hyperglycemia, associated with deficiency or resistance to insulin and shows abnormality in exocrine activity of pancreas. Pancreas is mixed gland that is both an endocrine and an exocrine gland with clusters of endocrinal, islet cell dispersed among exocrine acinar cells. Defects in islets cells in diabetes effect the exocrine secretion of the pancreas.

Methods: Hospital based case-control study was conducted. Total sample size was 388. Out of which 194 were known cases of type 2 diabetic patients attending Manipal Teaching Hospital for medical checkup whereas 194 were Non-Diabetic individuals with age and sex matched. Self-administer question was used to collected data from case and control. Three ml fasting blood samples were collected and centrifuged. Serum amylase was analyzed by using a semi-automated analyzer. All estimates data were analysis statistically by using SPSS 22.0 full version.

Results: Serum amylase levels were found significantly low in diabetic patients as compared to the Non-Diabetic (r = -0.313, p-value <0.001). Similarly, present study also showed negative correlation between serum amylase levels and duration of diabetes with Non-Diabetic (r = -0.388, p <0.001). Status of serum amylase and fasting sugar level was found to different among age groups, sex and ethnic groups.

Conclusions: The increasing in duration of diabetes decreases the level of serum amylase which suggests a possible exocrine-endocrine relationship in this disease. Similarly, the level of serum amylase and fasting blood sugar vary among age group, sex and ethnicity. Thus, measurement of serum amylase can be an additional informative parameter for the assessment of chronicity and progress of the illness as well as the response to therapy.

Keywords: Fasting blood glucose level, Type 2 diabetes mellitus, pancreatic functions, Serum Amylase

INTRODUCTION

Diabetes Mellitus (DM) is a metabolic disorder associated with hyperglycemia and derangement in insulin. An islet cell of pancreas secretes insulin. Type 2 diabetes is the most common form of diabetes. It does not use insulin properly i.e., resulting from the combination of resistance to insulin action and inadequate insulin resistance. According to the Central for Disease Control’s 2017, National Diabetes Statistics Report, there were around 1.5 million new total diabetes cases among adults in 2015. The 2016 Diabetes Profile has shown that 9.1 percent Nepali population are living with diabetes. The pancreas is a mixed gland comprises with exocrine portion making up the greatest volume of 84% while the endocrine part comprises 16% of it. Exocrine portion secrete amylase and lipase that helps in digestion of food particles. Acinar cells and islet cells are in close proximity with each other. Defect in islet cells observed in diabetes may disturb neighboring acinar cells of the pancreas. The pancreatic exocrine acinar cells produce several types of enzymes including amylase and lipase that helps in digestion of particular food particles. Endocrinal derangement observed in diabetes may interfere with the exocrine function of pancreas.

The amylase which leaks into circulation is excreted by the kidneys into urine whereas small amount of amylase is present in serum normally. As pancreas is a mixed gland i.e. exocrine and endocrine, it secretes amylase as enzyme and insulin as hormone. During diabetes there is insulin derangement and most of the insulin secreting cells are damaged which may affect the exocrine i.e. amylase secretion. Pancreatic endocrine and exocrine relation has been observed and insulin affects the amylase secretion via islet acinar cell axis. Insulin receptor are present in acinar cells and stimulates the amylase secretion. Some studies showed that low serum amylase values are associated with metabolic syndrome and diabetes. High value of amylase enzyme is seen in pancreatitis, pancreatic cancer and pancreatic duct obstruction. There are number of studies regarding high values of serum amylase in acute pancreatitis but very few studies are seen regarding significance of low serum amylase levels in clinical condition like Diabetes Mellitus.

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Till date very few research studies have been conducted on status of serum amylase in type 2 diabetic patients. Such types of studies had not been conducted in Pokhara, Nepal. Therefore, the aim of this study was to study the status of serum amylase in type 2 diabetic patients and the information may be useful for prediction the situation for further research.

**METHODS**

This study was hospital based case control study. The sample size was 388 out of them 194 were Diabetic and 194 were Non-Diabetic individuals (1:1 ratio case and control), conducted at Department of Clinical Biochemistry of Manipal Teaching Hospital in Pokhara from a period of September, 2019 to March, 2020. Ethical approval was obtained from Institutional Review Committee (IRC), Pokhara University Research Center, Kaski Nepal (Ref.No.78/076/077).

Similarly, the study was conducted among the people aged above 30 years on both genders who come for checkup at Manipal Teaching Hospital Pokhara, where cases were diabetic patients and controls were Non-Diabetic (Non-DM) such as care takers and hospital staffs who were willing to take participate on our research. Investigator asked verbally to them whether they had any history of diabetes or not. Then the individual who self-reported diabetes was considered as a sample for diabetic patients.

Questionnaire was pretested among 5% of confidentiality. Also, the blood glucose level was tested to validate it. All the subjects, including the controls, were fully informed about the study and informed consents were taken from each individual. Three ml fasting venous blood were collected from the subjects, blood were centrifuged and the serum was separated for analysis for the blood glucose and the serum amylase activity as per the routine procedure which was followed in the department. The sample analysis was carried out on a fully automated analyzer by using different reagent kits as per the procedure which was defined by the manufacturer. The estimation of fasting blood glucose was done by the glucose oxidase- peroxidase method and the amylase activity was measured by a photometric enzymatic method.

Proper coding of data collection tools and verification was done for completeness in the filled questionnaire. Data was checked, coded and analyzed by using SPSS (22.0 full version). Descriptive statistics (frequency, mean, standard deviation) was calculated and t test was used to compare the variables between the groups.

**RESULTS**

Among 194 diabetic patients there were 98 male (M) and 96 females (F) similarly out of 194 Non-Diabetic individuals male were 95 and female were 99. The mean age of Diabetic and Non-Diabetic were 58.39 ±13.12 and 58.17±13.54 respectively. Amylases level and sugar level was statically significant whereas, it was statically insignificant with age (Table 1).

<table>
<thead>
<tr>
<th>Characteristics of subjects</th>
<th>Diabetic n=194 M=98,F=96</th>
<th>Non-Diabetic n=194 M=95,F=99</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>58.17 ± 13.54</td>
<td>58.39 ± 13.12</td>
<td>0.8</td>
</tr>
<tr>
<td>Amylase level</td>
<td>65.24 ± 15.02</td>
<td>78.32 ± 35.20</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Glucose level</td>
<td>146.6 ± 71.0</td>
<td>111.4 ± 13.8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

There is negative correlation between serum amylase levels and fasting blood glucose levels in type 2 diabetic patients which shows when fasting blood glucose level increases, the serum amylase level decreases (Pearson’s correlation coefficient, r = -0.313, p< 0.001) (Figure-1).

![Figure 1: Correlation of serum amylase activity with fasting blood glucose levels in diabetic patients showing a negative correlation (r = -0.313).](image)

Similarly, there is also negative correlation between serum amylase levels and duration of diabetes which shows when duration of diabetes increases, the serum amylase levels decreases (Pearson’s correlation coefficient, r = -0.388, p<0.001) (Figure-2)
Out of 194 diabetic patients, 131 are hypertensive and 63 are non-hypertensive where hypertensive patients are found to be higher than non-hypertensive patients on comparing with mean serum amylase levels in figure 5.

Similarly in ethnic groups, mean serum amylase levels were found to be higher in Brahmin as compared to other groups in figure 6.

**DISCUSSION**

In diabetic patients, insulin resistance leads to an increase in the activity of anti-insulin hormones and atrophy of exocrine acinar cells. Thus, exocrine pancreatic enzyme synthesis and secretion is decreased. In our study, serum amylase showed negative correlation with duration of diabetes which was statistically significant. Similar results were also found by researchers, where the relationship between serum amylase and duration of diabetes was statistically significant and amylase in type 2 diabetic
subjects became more severely affected in long-standing cases of diabetes mellitus indicating that measuring serum amylase levels in diabetics may be used for understanding the progress of diabetes.15

In this study, we compared serum amylase and fasting blood sugar to correlate islet and acinar cell linkage which significantly shows low serum amylase level in type 2 diabetic patients as compared to that of healthy controls. We also found significantly higher Fasting sugar in type 2 Diabetic mellitus as compared to controls. The low serum amylase level in diabetes may reflect the impaired exocrine-endocrine interaction of the pancreas. Similar to our result some researcher demonstrated that serum activity in type II diabetes was higher than in type I diabetics.16 Defects in insulin secretion and function leads to hyperglycemia and may affect the enzyme synthesis and release from exocrine pancreas.17 Uncontrolled diabetes mellitus patients are unable to transport glucose into fat and muscle cells and have glucose intolerance.18

Similar to our study some authors suggested that low serum amylase was associated with type 2 diabetes.19 In our study we found significantly higher Fasting blood sugar in type 2 Diabetic as compared to healthy individuals. The low serum amylase level in diabetes effect connection of exocrine-endocrine part of the pancreas because pancreas is a mixed gland i.e. it has both endocrine and exocrine gland due to which degradation in exocrine cell and its secretion, it also effect the endocrinial portion. However, in contrast to our results, there was another study found significant increase in serum amylase level in diabetic group as compared to the control group.20

Some Author suggested that Low level of amylase in the body is mostly resulted due to consumption of high amounts of carbohydrates. This is the case with amylase deficiency in people with fat intolerance. Amylase catalyzes starch and complex carbohydrates. So, the higher the amount of these nutrients in the body, the more is the requirement of amylase. Eventually, the level of amylase falls down from the normal recommended level, thus manifesting amylase deficiency symptoms. 21, 22

CONCLUSION

The increasing in duration of diabetes decreases the level of serum amylase which suggests a possible exocrine-endocrine relationship in this disease. Similarly, the level of serum amylases and fasting blood sugar vary among age group, sex and ethnicity. Thus, measurement of serum amylase can be an additional informative parameter for the assessment of chronicity and progress of the illness as well as the response to therapy.

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